

REMARKS

These remarks are in response to the Office Action mailed May 17, 2007. Claims 28, 31, 35-44, 49 and 53 have been amended. Support for amended Claim 28 can be found, for example, in the Summary of the Invention and in originally filed Claims 28, 32, 33, and 41. Amendments to the remaining claims are provided to maintain consistency of terminology. Support for amendments to Claims 31, 35-44 and 53 can be found, for example, in original Claim 30. Claims 1-27 and 64-69 were previously cancelled without prejudice or disclaimer. In the present paper, Claims 29-30, 32-33, 45-48, 52, 54, 57, 60-63 and 70-72 are cancelled without prejudice or disclaimer. Subsequent to the entry of the present amendment, Claims 28, 31, 34-44, 49 and 53 are pending and examination on the merits is respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph (enablement)

Claims 28-49, 52-54, 57, 60-63 and 70-72 are rejected under on 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make or use the invention. Applicants respectfully traverse the rejection as it applies to the pending claims. Claims 29-30, 32-33, 45-48, 52, 54, 57, 60-63 and 70-72 have been cancelled rendering the rejection moot as to such claims.

Applicants respectfully submit that MPEP §2164.08 states “[a]ll that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art.” Further, “[t]he Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation’.” *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. *In fact, what is well-known is best omitted* [emphasis added]. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

Specifically, the Office Action alleges that with the exception of claims 48-49 and 71-72, which limit the envelope virus to herpes virus (herpes virus 1), the claims are not limiting to a specific envelope virus. The Office Action further alleges that the full breadth of the instant claims encompass all envelope viruses. Applicants respectfully submit that envelope viruses

were well known at the time the present application was filed to possess common character with regard to structure and function among various types of viruses. However, without acquiescing to the rationale of the Office, Applicants have amended the claims to expedite prosecution of the present application. The claims, as amended recite a "herpes virus".

The Office further alleges that the present application lacks disclosure of *in vivo* or dermal use of cyclodextrin to treat herpes or infection by other envelope viruses or any microorganism. Without acquiescing to the rationale of the Office Applicants have amended the claims to expedite prosecution of the present application. As amended, the claims recite a method for "reducing viral load of a herpes infection in an interstitial space of a mammal". Additionally, Applicants respectfully submit that the specification clearly teaches the skilled artisan that beta cyclodextrin decreases vial load of certain types of viruses. For example, Applicants respectfully direct the Examiner's attention to page 5, lines 1-12 of the specification as filed describes the mechanism in which the present invention treats or prevents viral transmission. Accordingly, Applicants respectfully submit that the skilled artisan would be enabled in treating or preventing transmission of envelope virus in light of the specification as filed.

With respect to the allegation that the art did not recognize the therapeutic, *in vivo* or dermal use of cyclodextrin to treat envelope viruses at the time of filing, Applicants respectfully submit herewith Exhibit 1 (*J. Virology*, v. 77, n.15 (2003), pp. 8237-8248, received October 2002), an article, which describes the use of cyclodextrins for prevention of viral transmission. Exhibit 1 describes in pertinent part:

[m]ethyl- β -cyclodextrin (M β CD), which disrupts DIMS (detergent-insoluble microdomains) by depleting cells of cholesterol, inhibits virus infection and that this inhibition was partially reversed by partially restoring cholesterol levels in cells, suggesting that M β CD inhibition of virus infection was mediated by removal of cellular cholesterol. (see Abstract of Exhibit 1).

Applicants note that the results described in Exhibit 1 clearly demonstrate that the art, at the time the application was filed, recognized the therapeutic, *in vivo* use of cyclodextrin to treat

enveloped viruses. Further, Applicants submit that the level of skill in the art, at the time of filing, was such that the skilled artisan would be able to practice the present invention, in view of the specification, without undue experimentation.

Accordingly, withdrawal of rejection of pending claims 28, 31, 34-44, 49 and 53 under 35 U.S.C. §112, first paragraph is respectfully requested.

Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

Claims 28-49, 52-54, 57, 60-63 and 70-72 are rejected under the judicially created doctrine of obviousness double patenting allegedly over claim 26 of copending Application No. 10/637,793 (U.S. Publication No. 20050015847 hereafter “the ‘793 Application”). Applicants respectfully traverse the rejection as it applies to the pending claims. Claims 29-30, 32-33, 45-48, 52, 54, 57, 60-63 and 70-72 have been cancelled rendering the rejection moot as to such claims.

A Terminal Disclaimer, disclaiming any patent term of the present application that may extend beyond the term of any patent issued in the copending ‘793 Application is submitted herewith. Accordingly, Applicants respectfully request withdrawal of the double patenting rejection.

Claims 28-49, 52-54, 57, 60-63 and 70-72 are rejected under the judicially created doctrine of obviousness double patenting allegedly over claim 1 of copending Application No. 11/605,037 (U.S. Publication No. 20070088000 hereafter “the ‘037 Application”). Applicants respectfully traverse the rejection as it applies to the pending claims. Claims 29-30, 32-33, 45-48, 52, 54, 57, 60-63 and 70-72 have been cancelled rendering the rejection moot as to such claims.

A proper nonstatutory obviousness-type double patenting rejection requires two or more patents or applications to have at least one common inventor and be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement (see MPEP 804).

Applicants respectfully submit that pursuant to an obligation to assign, Dr. George Scheele has assigned his rights in the present application to La Jolla Biosciences and Dr. James Hildreth has assigned his rights in the present application to The Johns Hopkins University School of Medicine. Further pursuant to an obligation to assign, Dr. James Hildreth has assigned his right in the '037 Application to The Johns Hopkins University School of Medicine. As such, the present application, does not share common ownership with the '037 Application. Because the subject matter of the present application and that of the '037 Application does not currently share common ownership with the '037 Application, Applicants respectfully submit that the rejection is incorrectly applied. Accordingly, Applicants request withdrawal of the rejection.

In re Application of:
Scheele and Hildreth
Application No.: 10/625,090
Filed: July 22, 2003
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Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge a total of \$590.00 as payment for the three-month Extension of Time fee (\$525.00) and Terminal Disclaimer fee (\$65.00), for small entity, to Deposit Account No. 07-1896. Additionally, the Commissioner is authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

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